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April 24, 2003

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

21 CFR PART 1

[DOCKET NO. 02N-0275]

RIN 0910-AC38

Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is proposing a regulation that provides procedures for the detention of an article of food, if an officer or qualified employee of FDA has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals ("administrative detention"). The proposed regulation implements section 303 of the Public Health Security and Bioterrorism Preparedness Act of 2002 ("the Bioterrorism Act"), which authorizes the use of administrative detentions and requires regulations establishing procedures for instituting on an expedited basis certain enforcement actions against perishable

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foods subject to a detention order.

DATES: Submit written or electronic comments by [insert date 60 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT:

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I. Background and Legal Authority

The events of September 11, 2001, highlighted the need to enhance the security of the United States food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act") (Public Law 107-188), which was signed into law on June 12, 2002. The Bioterrorism Act includes a provision in title III (Protecting Safety and Security of the Food and Drug Supply), Subtitle A (Protection of Food Supply), section 303, which amends section 304 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331 et seq.) by adding subsection (h) to provide that an officer or qualified employee of FDA may order the detention of any article of food that is found during an inspection, examination, or investigation under the act if the officer or qualified employee has credible evidence or information indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals. This provision also requires the Secretary of Health and Human

Services (Secretary) to provide by regulation procedures for instituting on an expedited basis certain enforcement actions against perishable food subject to a detention order. Section 303 of the Bioterrorism Act also amends the act by adding a new prohibited act as subsection (bb) to section 301.

The major components of section 303 of the Bioterrorism Act are as follows:

- Criteria used to trigger an administrative detention: Amends section 304 of the act to authorize an officer or qualified employee of FDA to order the detention of any article of food that is found during an inspection, examination, or investigation under the act, if the officer or qualified employee has credible evidence or information indicating such article presents a threat of serious adverse health consequences or death to humans or animals.

- Approval required: The Secretary, or an official designated by the Secretary, must approve the detention order. An "official designated by the Secretary" means the District Director of the district where the detained article of food is located, or an official senior to such director.

- Period of detention: The detention period will be for a

reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary to enable the Secretary to institute a seizure or injunction action.

- Required rulemaking: The Secretary must by regulation provide for procedures for instituting certain enforcement actions on an expedited basis with respect to perishable food subject to a detention order.

- Security of detained article of food: The detention order may require that the detained article of food be labeled or marked as detained. The order must require the removal of the detained article of food to a secure facility, as appropriate.

- Appeal procedure: Any person who would be entitled to claim the detained article of food if such article were seized may appeal the detention order to the Secretary. Within 5 days after such appeal is filed, after providing opportunity for an informal hearing, the Secretary must confirm or terminate the detention order. The appeal process terminates if the Secretary institutes an action for seizure or injunction regarding the article of food involved. Confirmation of a

detention order is considered a final agency action.

- Prohibited act: Amends section 301 of the act making it a prohibited act to transfer a detained article of food in violation of a detention order, or to remove or alter any mark or label required by the detention order to identify the article of food as detained.

Section 303 of the Bioterrorism Act also includes a provision authorizing temporary holds at ports of entry that will not be addressed in this proposed regulation, but through separate guidance that FDA plans to develop and issue. The temporary hold provision authorizes FDA to request the Secretary of Treasury to institute a temporary hold for up to 24 hours on an article of food offered for import at a U.S. port of entry if FDA has credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals, and FDA is unable immediately to inspect, examine, or investigate such article. FDA has received comments on the temporary hold provision in the public docket (docket number 02N-0275). FDA plans to consider these comments in developing guidance on the temporary hold provision.

FDA is proposing to amend Title 21 of the Code of Federal Regulations (CFR) by establishing a new subpart to Part 1 consisting of Subpart K—Administrative Detention of Food for Human or Animal Consumption. In this proposed rule, we describe the procedures for how FDA will detain an article of food and the process for appealing a detention order. We also address procedures for instituting on an expedited basis certain enforcement actions with respect to detained perishable foods. This proposed rule also makes a conforming amendment to 21 CFR part 16 (Regulatory Hearing Before the Food and Drug Administration).

The administrative detention process described in this proposed rule is modeled after FDA's medical device administrative detention regulation found at 21 CFR 800.55. FDA believes that this process has been effective and efficient for medical device administrative detentions and should also work well for administrative detentions of food. In addition, using the medical device regulations as a model will be helpful to the agency as field offices are familiar with this detention process and training will not need to be as extensive.

Section 303 of the Bioterrorism Act provides for an opportunity for an informal hearing as part of the appeal

process. 21 CFR part 16 sets out FDA's informal hearing procedures and provides that its procedures apply when the act or FDA regulations provide for an opportunity for a hearing and no specific hearing regulations exist (see 21 CFR 16.1(b)). Proposed § 1.403 states that any informal hearing held on an appeal of a detention order will be conducted in accordance with 21 CFR part 16 except as noted therein.

Although section 303 of the Bioterrorism Act requires FDA only to promulgate ~~regulations~~ regulations establishing procedures for instituting on an expedited basis certain enforcement actions ~~for instituting expedited procedures~~ against~~for~~ perishable food subject to a detention order, FDA also is proposing in this regulation to describe the procedures for how FDA will detain ~~all~~ both perishable and nonperishable articles of food and the process for appealing a detention order. If FDA did not establish other requirements for the process for appealing a detention order in this proposed regulation, it would be difficult for FDA to meet certain requirements in section 303 of the Bioterrorism Act. For example, section 303 of the Bioterrorism Act requires FDA, after providing an opportunity for an informal hearing, to confirm or terminate a detention order within ~~five~~ 5 days after the date of appeal. Two of the requirements in this proposed rule would be to impose a deadline

for filing an appeal and a limitation on the length of the informal hearing (see proposed §§ 1.402 and 1.403). These proposed requirements are intended to ensure that FDA meets section 303's timing requirements. FDA is proposing to codify the procedures for how FDA will detain an article of food to clarify our procedures for the public and to follow FDA's model for the administrative detention of medical devices that has its procedures codified at 21 CFR 800.55. FDA is proposing to incorporate these provisions in a regulation instead of a guidance document to make them enforceable since guidance documents are not binding.

FDA wants to make clear that this proposed rule does not implement section 801 of the act, despite its use of the term "detention". As explained in this preamble, this proposed rule implements section 303 of the Bioterrorism Act, which amends section 304 of the act. This amendment grants FDA the authority to detain food upon credible evidence or information of a threat of serious adverse health consequences or death to humans or animals. FDA has had similar authority for medical devices under section 304(g) of the act since 1976, and usually refers to this authority as "administrative detention" (21 CFR 800.55). Section 801(a) of the act provides that FDA shall refuse the admission of any article of food that has been imported or

offered for import that appears, among other things, to be adulterated or misbranded under the act, based on physical examination or otherwise. Under section 801(a), before FDA refuses admission to an article that appears violative, importers are provided with a Notice of Hearing on Refusal of Admission, which notifies them that the article may be subject to refusal of admission, and provides them with an opportunity to introduce testimony and establish that the article is fully in compliance with the act (21 CFR 1.94). FDA refers to this administrative process concerning imports as detention (see FDA Regulatory Procedures Manual (RPM), Chapter 9). Because of the authorities available to the FDA and the United States Customs Service to control imported food subject to section 801(a) of the act, FDA does not expect to frequently use administrative detention under section 303 of the Bioterrorism Act to control such imported food.

Section 304(h) of the act, as added by section 303 of the Bioterrorism Act, provides that: "An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this Act conducted by such officer or

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qualified employee, if the officer or qualified employee has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals. This language does not include a limitation similar to that in section 304(g) of the act which provides for administrative detentions of devices during inspections conducted under section 704 of the act, a provision of the act that has an interstate commerce component. In addition, the prohibited act related to administrative detention of food, section 301(b) of the act, unlike some other prohibited acts in section 301, does not include an interstate commerce component. Therefore, FDA tentatively concludes that all food would be subject to administrative detention under section 304(h) of the act, whether or not the food enters interstate commerce. Because a bioterrorist threat involving food or other food-related emergencies would have the same effect on the public health regardless of whether the food had originated from an out of state source, FDA believes that administrative detention should apply to all food, whether or not the food was in interstate commerce. FDA recognizes, however, that section 304(h) of the act is not clear in this regard. For example, section 304(h) includes references to certain enforcement provisions of the act, such as section 304(a) of the act, an

enforcement provision that includes an interstate commerce requirement. Because this is an important and controversial issue, the agency is seeking comment on whether its tentative conclusion that it has authority to administratively detain food in intrastate commerce is correct and, if so, whether FDA should use that authority. FDA also seeks comments on the amounts and types of food that would only be in intrastate commerce.

This proposed rule complies with Section 315 of the Bioterrorism Act entitled, "Rule of Construction," which states that nothing in Title III of the Bioterrorism Act, or an amendment made by Title III, shall be construed to alter the jurisdiction between the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services under applicable statutes and regulations. Accordingly, this proposed rule does not apply to food regulated exclusively by the USDA under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.). However, food that is jointly regulated by FDA and USDA would be subject to this proposed rule. An example of a food that is jointly regulated by FDA and USDA is frozen t.v. dinners containing both meat and fish.

In addition to section 303 of the Bioterrorism Act, which amends the act as described previously in section I. of this document, FDA is relying on section 701(a) of the act (21 USC 371(a)) in issuing this proposed rule. Section 701(a) authorizes the agency to issue regulations for the efficient enforcement of the act.

II. Preliminary Stakeholder Comments

On July 17, 2002, FDA sent an open letter to members of the public interested in food issues outlining the four provisions of title III of the Bioterrorism Act which require FDA to issue regulations in an expedited time period, and FDA's plans for implementing them (see http://www.cfsan.fda.gov/~dms/sec-ltr.html). In the letter, FDA invited stakeholders to submit comments to FDA by August 30, 2002, for FDA's consideration as it developed this proposed rule. FDA also held several meetings with representatives of industry, consumer groups, other federal agencies, and foreign embassies after sending out the July 17, 2002, letter in order to solicit stakeholder comments. In response to these solicitations, FDA received a number of comments regarding section 303 of the Bioterrorism Act.

FDA has considered all the comments received by August 30,

2002. FDA will consider all comments we have received so far with the comments we receive during the public comment period for this proposed rule in developing the final rule.

Some of the significant comments FDA received on or before August 30, 2002, include:

- The regulations should apply to all foods within FDA's jurisdiction, (e.g., processed food, fresh agriculture and dietary supplement products).
- The written notice of detention should describe the article of food that has been detained, the quantity of the food, its location, and the basis for the detention. A written notice of detention also should include a written explanation of the appeal right and information that will enable a person entitled to appeal to understand how to file such an appeal.
- FDA's regulations should ensure that if a detained article of food is moved to a secure facility, the food will be maintained under temperature, humidity and other conditions that will maintain the value and quality of the food.
- A period of 24 to 48 hours from the time of request to the time of holding a hearing is the appropriate timeframe given the short life of many perishable foods.

- Any regulations with respect to detention of food should specify how disputes and resolutions will be handled in order to help prevent spoilage of detained food.
- When an appeal against the detention is filed, FDA should deal with it expeditiously within a fixed period of time to minimize the impact on private businesses.
- An appellant should be entitled to file a written statement of his or her position. The findings of the Secretary after the hearing should be set forth in writing since the Bioterrorism Act provides that the Secretary's decision is "final agency action" under the Administrative Procedure Act, which is judicially reviewable.
- A sanction should be imposed if the detained product is moved before the detention period has expired or has been terminated.

III. The Proposed Regulation

This proposed rule implements the administrative detention provision in section 303 of the Bioterrorism Act. If the regulation is made final as proposed, administrative detention, together with the proposed rules implementing section 305 (registration), section 306 (recordkeeping), and section 307

(prior notice) of the Bioterrorism Act, will enable FDA to act quickly in responding to a threatened or actual bioterrorist attack on the United States food supply or to other food-related emergencies.

In establishing and implementing this proposed rule, FDA will comply fully with its international trade obligations, including applicable World Trade Organization (WTO) agreements and the North American Free Trade Agreement ("NAFTA"). For example, FDA believes this proposed rule is not more trade-restrictive than necessary to meet the objectives of the Bioterrorism Act. The criteria FDA would use to order a detention are taken directly from the Bioterrorism Act and are the same for both domestic and foreign articles of food.

A. Highlights of Proposed Rule

The key features of this proposed rule are as follows:

- An officer or qualified employee of FDA may order the detention of domestic or imported food for up to 30 days if FDA has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals.

- The FDA District Director in the district in which the article of food is located or an official senior to such director must approve a detention order.
- FDA may require that the detained article of food be labeled or marked as detained with official FDA tags or labels. The FDA tag or label will include, among other information, a statement that the article of food must not be consumed, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative.
- A violation of a detention order or the removal or alteration of the tag or label is a prohibited act.
- FDA will state in the detention order the location and any applicable conditions under which the food is to be held.
- FDA may direct that the article of food be moved to a secure facility, if appropriate. An article of food moved to a secure facility remains under detention before, during, and after such movement.
- FDA may approve a request for a limited conditional release of a detained article of food for purposes of destruction, movement to a secure facility, preservation of the detained article of food, or any other purpose that FDA believes is

appropriate. An article of food transferred under a limited conditional release remains under detention before, during, and after the transfer.

- Any transfer of a detained article of food in violation of a detention order is a prohibited act.
- Any person who would be entitled to be a claimant for the article of food, if seized, may appeal a detention order and, as part of that appeals process, may request an informal hearing. If a hearing is granted, an FDA Regional Food and Drug Director or another official senior to an FDA District Director will serve as the presiding officer of the hearing.
- The proposed rule includes appeal and hearing timeframes for both perishable and non-perishable detained articles of food.
    - Perishable food:
        - An appeal must be filed within two calendar days of receipt of the detention order.
        - If a hearing is requested in the appeal, and FDA grants the request, the hearing will be held within two calendar days after the date the appeal is filed.

- FDA's decision on appeal will be issued five days after the appeal is filed.

- Non-perishable food:
  - A notice of intent to file an appeal and to request a hearing must be filed within four calendar days of receipt of the detention order.
  - An appeal must be filed within ten calendar days of receipt of the detention order.
  - If a hearing is requested in the notice of intent and appeal, and FDA grants the request, the hearing will be held within three calendar days after the appeal is filed.
  - FDA's decision on appeal will be issued five days after the appeal is filed.

- The proposed expedited procedures for certain enforcement actions with respect to perishable foods require FDA to send a seizure recommendation to the Department of Justice within four calendar days after the detention order is issued, unless extenuating circumstances exist.

- Confirmation of a detention order by the FDA presiding officer is considered final agency action.

B. General Provisions

1. What definitions apply to this subpart? (Proposed § 1.377)

Proposed § 1.377 describes the definitions that apply to this subpart and states that the definition of terms that appear in section 201 of the act apply to such terms when used in this subpart.

Proposed § 1.377 also defines specific terms used in the proposal.

- "Act" means the Federal Food, Drug, and Cosmetic Act.
- "Authorized FDA representative" means the FDA District Director in whose district the article of food involved is located or an FDA official senior to such director. FDA's Office of Regulatory Affairs (ORA) is responsible for FDA's field operations and compliance related functions. The ORA field organization is divided into regional offices, which are headed by Regional Food and Drug Directors. The regions are broken down into district offices, which are headed by

District Directors. A Regional Food and Drug Director is an FDA official senior to an FDA District Director.

- "Calendar day" means every day shown on the calendar. This term includes weekend days.
- "Food" has the meaning given in section 201(f) of the act (21 U.S.C. 321(f)). That definition is: "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." FDA also is proposing to include some examples of products that are considered food under section 201(f) of the act. These examples include, but are not limited to: fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals (such as hogs and elk); bakery goods; snack foods; candy; and canned foods. "Substances that migrate into food from food packaging" include immediate food packaging or components of immediate food packaging that are intended for food use. Outer food packaging is not considered a substance that migrates into

food.

- "Perishable food" means food that is not heat-treated; not frozen; and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than seven days under normal shipping and storage conditions. This perishable food definition has been modeled after the current RPM definition of "perishable commodity". Examples of perishable foods include, but are not limited to fluid milk (but not ultrapasteurized); live fish, lobster, crab, other crustaceans, shellfish; and fresh fruits and vegetables.

We decided to use the RPM definition of "perishable commodity" as the basis for the definition of "perishable food" because the RPM definition is commonly used and understood by both industry and FDA. Furthermore, we believe this definition is appropriate in light of the five day (maximum) deadline for FDA to issue a decision on an appeal of a detention. Under the proposed deadlines for appeals involving the detention of a perishable food, FDA would issue a decision on an appeal prior to the expiration of the seven day period. We believe the time frames proposed here offer the best protection to appellants and products.

We invite comments and supporting data on how to best define

"perishable food" for the purposes of this proposed rule.

- "We" means the United States Food and Drug Administration.
- "Working day" means any day from Monday through Friday, excluding federal holidays.
- "You" means any person who received the detention order or that person's representative.

2. What criteria does FDA use to order a detention? (Proposed § 1.378)

Proposed § 1.378 states the criteria FDA would use to order a detention. These criteria are taken directly from section 303 of the Bioterrorism Act. FDA may order a detention of an article of food that is found during an inspection, examination, or investigation under the act if an officer or qualified employee of FDA has credible evidence or information indicating that an article of food presents a threat of serious adverse health consequences or death to humans or animals.

The Bioterrorism Act articulates a standard of "credible evidence or information" for determinations of whether the evidence or information indicates that an article of food presents a threat of serious adverse health consequences or death to humans or animals. "Credible evidence or information" is an evidentiary standard that in simplest terms means evidence or

information that is "worthy of belief or confidence; trustworthy." See Webster's Unabridged Dictionary (1998 ed.) (definition of "credible"). Although various statutes and regulations use this or a similar standard, and courts have invoked or applied the standard of credible evidence or information in a large number of decisions, no precise definition of the standard exists. Instead, determinations of what constitutes credible evidence or information have been made on a case-by-case basis. Likewise, FDA has administered evidentiary standards under other provisions of the act (see e.g., section 304(g)) on a case-by-case basis without further defining those standards in regulation. We believe that a similar approach here is appropriate. In applying the credible evidence or information standard to administrative detention, FDA may consider a number of factors including, but not limited to, reliability, reasonableness, and the totality of the facts and circumstances.

The officers or qualified employees of FDA who may order a detention include, but are not limited to, FDA field investigators, other government employees commissioned or deputized by FDA, and FDA employees who have security clearance to receive national security information. An "authorized FDA representative" as defined in proposed § 1.377, would have to approve a detention order before the FDA officer or qualified

employee may order a detention.

3. How long may FDA detain an article of food? (Proposed § 1.379)

Proposed § 1.379 sets forth the period of administrative detention, (i.e., the length of time an article of food may be detained), consistent with the requirements of section 303 of the Bioterrorism Act. The period of administrative detention must be a reasonable period that may not exceed 20 calendar days after the detention order is issued, unless it is determined that a greater period is required either to seize the article of food or to institute injunction proceedings. When a greater period of time is necessary, the Bioterrorism Act provides that an article of food may be detained for up to ~~ten~~ 10 additional calendar days. The authorized FDA representative, defined in proposed § 1.377, may approve the additional ~~ten~~ 10 days of detention at the time the detention order is issued, or at any time within the initial 20 calendar day period, by amending the detention order.

Proposed § 1.379 states that the entire detention period may not exceed 30 calendar days in total. This proposed section also allows the authorized FDA representative, in accordance with proposed § 1.384, to approve the termination of a detention order

before the expiration of the detention period. FDA intends to proceed as expeditiously as possible to resolve all issues involved with particular administrative detentions.

4. Where and under what conditions must the detained article of food be held? (Proposed § 1.380)

Proposed § 1.380(a) requires you to hold the detained article of food in the location and under the conditions specified by FDA in the detention order. Use of appropriate storage conditions, such as temperature, humidity, and other conditions may be necessary to protect the safety and wholesomeness of the detained article of food. This proposed requirement is consistent with the legislative history of the Bioterrorism Act (see H. Conf. Rept. No. 107-481, at 131 (2002)).

In proposing § 1.380(a), we also considered the experience that states have had with embargoes. As described in comments from states familiar with embargoing food on behalf of FDA or on their own initiative, states have ordered food embargoed and have provided requisite conditions that must be maintained while the food is embargoed, e.g., segregation from other products in the same warehouse.

In proposed § 1.380(b), the detained article of food must be moved to a secure facility if FDA determines that such movement is appropriate. FDA's determination of whether it is appropriate

to require movement of a detained article will depend, in part, on whether we believe there is danger of the detained article entering the stream of commerce. FDA will make such determinations on a case-by-case basis considering several factors, including the adequacy of security where the detained article is located, and the ability to prevent the movement of the food. For example, if it appears likely that the detained food would be diverted, we would require the food to be moved to a secure facility. However, if the storage conditions are such that there appears to be no danger of the detained article of food moving into the stream of commerce, we would decide to keep the article of food detained at its current location.

There may be instances where we relocate the detained article of food to a secure facility. For example, FDA may not be confident that parties involved will adhere to a detention order. Rather than risk losing control over the detained article of food, FDA would relocate the detained article of food. There may be other situations where FDA decides to relocate the detained article to a secure facility.

Proposed § 1.380(b), also states that a detained article of food remains under detention before, during, and after movement to a secure facility, if FDA has requested such movement. As such, we will also state in the detention order any applicable

conditions of transportation of an article of detained food. This may include determinations that the article to be removed to a secure facility must be moved under certain conditions. Similar to determinations of whether to require that food be removed to a secure facility, determinations of the appropriate conditions of transportation will be made on a case-by-case basis.

Proposed § 1.380(c) requires you to have received a limited conditional release under proposed § 1.381(c) before you move the detained article of food to a secure facility.

Proposed § 1.380(d) requires you to ensure that any required tags or labels under § 1.382 accompany the detained article during and after movement to the secure facility. This requirement applies until FDA terminates the detention order or the detention period expires, whichever occurs first, unless otherwise permitted by the authorized FDA representative.

Proposed § 1.380(e) provides that the movement of an article of food in violation of a detention order issued under § 1.393 is a prohibited act under section 301 of the act.

5. May a detained article of food be delivered to another entity or transferred to another location? (Proposed § 1.381)

Proposed § 1.381 describes whether an article of food subject to a detention order can be delivered to another entity or transferred to another location. Proposed § 1.381(a) states that a detained article of food may not be delivered to another entity pursuant to the execution of a bond. Similarly, this proposed section also states that an article of food detained under section 303 of the Bioterrorism Act may not be delivered to any of its importers, owners, or consignees pursuant to section 801(b) of the act. The provisions found in this proposed paragraph are consistent with section 303 of the Bioterrorism Act, and are designed to keep foods that present a threat of serious adverse health consequences or death from moving in commerce.

Proposed § 1.381(b) prohibits, except as provided in proposed § 1.381(c), the transfer of a detained article of food within or from the place where it has been detained, or from the place to which it was moved, until an authorized FDA representative releases the article of food under proposed § 1.384 or the detention period expires under proposed § 1.379, whichever occurs first. This provision is necessary to ensure that the article of food subject to a detention order is not released into commerce.

Proposed § 1.381(c) provides that an authorized FDA

representative may approve, in writing, a request for a limited conditional release of the detained article of food for any of the following purposes:

1. To destroy the article of food;
2. To move the detained article of food to a secure facility as described in the detention order;
3. To maintain or preserve the integrity or quality of the article of food; or
4. For any other purpose that the authorized FDA representative believes is appropriate in that case.

A limited conditional release of a detained article of food will be considered only in rare circumstances and only for the purposes described. We do not envision authorizing a limited conditional release under many circumstances because any movement increases the risk of inappropriate or unauthorized movement of detained articles of food into commerce. In order to decrease the chance of detained articles of food moving into commerce, the food should not be moved unless absolutely necessary. However, we recognize there may be cases where some movement is necessary. For example, it may be necessary to take steps to preserve the article of food until the detention is resolved, e.g., movement of a detained article of food from refrigerated storage to a freezer. This proposed section would allow such action in those

limited circumstances that the agency finds appropriate.

As noted below, an article of food subject to a limited conditional release is still subject to detention and the requirements of this proposed rule.

Proposed § 1.381(d) requires you to submit a request for a limited conditional release in writing to the authorized FDA representative who approved the detention order. Your request must state the following:

- Reasons for movement;
- Exact address of and location in the new facility (or the new location within the same facility) where the detained article of food will be transferred;
- Explanation of how the new address and location will be secure, if FDA has directed that the article of food be detained in a secure facility; and
- Explanation of how the article of food will be held under any applicable conditions described in the detention order.

If your request is for the purpose of destroying the detained article of food, you also must submit a verified statement identifying the ownership or proprietary interest you have in the detained article of food. Under Federal Rules of Civil Procedure,

Supplemental Rule C(6)(a), a person who asserts an interest in or right against property that is the subject of a seizure action in federal court must file a verified statement identifying the interest or right. The purpose of this requirement is to minimize the possibility that the detained article of food would be released for destruction to a person without the proper ownership or proprietary interest in the food.

Proposed § 1.381(e) states that a detained article of food remains under detention before, during, and after the transfer under a limited conditional release. Accordingly, we will prescribe applicable transportation conditions to an article transferred under a limited conditional release. This section also provides another security measure to prevent the detained article of food from moving into commerce. That is, we also require FDA supervision of all transfers of detained articles of food made under a limited conditional release, unless FDA declines such supervision in writing. If FDA declines such supervision, you will be required to immediately notify in writing the authorized FDA representative who approved the limited conditional release, that the article of food has reached its new location, and the specific location of the detained article of food within the new location. Such notification may be in the form of a fax, email, or other form agreed to by the

authorized FDA representative.

Proposed § 1.381(f) requires you to ensure that any tags or labels required under proposed § 1.382 accompany the detained article of food during and after movement. If FDA labels or marks the detained article of food under proposed § 1.382, this proposed provision would require that the tags or labels remain with the article of food until FDA terminates the detention order or the detention period expires, whichever occurs first, unless otherwise permitted by the approving official.

Proposed § 1.381(g) provides that the transfer of an article of food in violation of a detention order issued under proposed § 1.393 is a prohibited act under section 301 of the act. This proposed provision is consistent with the statutory language in section 303 of the Bioterrorism Act.

6. What labeling or marking requirements apply to a detained article of food? (Proposed § 1.382)

Proposed § 1.382 describes the labeling or marking requirements that apply to a detained article of food. This proposed section states that the officer or qualified employee of FDA who issues the detention order may label or mark the detained article of food with official FDA tags or labels that include the following information:

- A statement that the article of food is detained by the United States Food and Drug Administration in accordance with section 304(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(h));
- A statement that the article of food must not be consumed, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative;
- A statement that the violation of a detention order or the removal or alteration of the tag or label is a prohibited act under section 301 of the act, punishable by fine or imprisonment or both; and
- The detention order number, the date and hour of the detention order, the detention period, and the name of the officer or qualified employee of FDA who issued the detention order.

Any label or mark of detention will be attached as appropriate given the circumstances. In some instances, the mark or label may be attached to the food container, while in other instances, the mark may be fastened to a packing container. Where the agency cannot mark or label a container or packing container, a mark or label may be attached to accompanying documents. FDA may use other means of marking or labeling as

appropriate or necessary. Once the detained article is released, or the detention period expires, FDA would remove, or authorize the removal of, the required labels or tags, as described in proposed § 1.384. Accordingly, we would not expect the proposed labeling and marking provision to impair the future ability to distribute or market the article of food if the detention order is terminated.

7. What expedited procedures apply when FDA initiates a seizure action against a detained perishable food? (Proposed § 1.383)

Section 303 of the Bioterrorism Act directs the Secretary to promulgate procedures for instituting certain judicial enforcement actions on an expedited basis with respect to perishable food subject to a detention order. This provision directs FDA to promulgate procedures for instituting on an expedited basis seizure actions under section 304(a) of the act, or injunction actions under section 302 of the act, or both. We have concluded that it is appropriate to focus on procedures to institute seizure actions on an expedited basis because a seizure is the most efficient judicial action for rapid control of a violative article of perishable food.

Proposed § 1.383 describes FDA's procedure for sending a seizure recommendation under section 304(a) of the act to the Department of Justice (DOJ) for a perishable food (defined in proposed § 1.377) subject to a detention order. We propose to send the seizure recommendation to DOJ within four calendar days after the detention order is issued, unless extenuating circumstances exist. If the fourth calendar day is not a working day when the government is open for business, we will advise the DOJ of our plans to recommend a seizure action on the last working day before the fourth calendar day and send the recommendation as soon as practicable on the first working day that follows. For example, if a detention order is issued on a Wednesday, the fourth calendar day would be the following Sunday. Because Sunday is a non-working day, we would advise the DOJ of our plans to recommend a seizure action on Friday and would send the recommendation as soon as practicable on the following Monday.

For purposes of this proposed section, extenuating circumstances include, but are not limited to, instances when the results of confirmatory testing or other evidentiary development require more than four calendar days to complete.

Proposed § 1.383 is designed to accelerate the procedure for seizure recommendations and takes into account the seven day

timeframe in the proposed definition of "perishable food." As noted previously in section III. B. 7. of this proposed rule, we have focused our implementation of this provision of section 303 of the Bioterrorism Act on seizure recommendation procedures. Use of injunctive relief may be appropriate in some circumstances involving detained perishable foods. However, expedited procedures for instituting injunction actions would not accelerate the judicial control of a particular violative article of perishable food as much as expedited procedures for seizure actions.

We invite comment on this or other procedures that would address concerns about expedited enforcement actions with respect to perishable food.

8. When does a detention order terminate? (Proposed § 1.384)

Under proposed § 1.384, an authorized FDA representative will issue a detention termination notice releasing the detained article of food if FDA decides to terminate a detention order or the detention period expires. FDA will issue the detention termination notice to any person who received the detention order or that person's representative. FDA also will remove, or authorize the removal of, the required labels or tags attached

under proposed § 1.382. If FDA fails to issue a detention termination notice and the detention period expires, the detention order is deemed to be terminated.

C. How does FDA order a detention?

1. Who approves a detention order? (Proposed § 1.391)

Proposed § 1.391 requires that an authorized FDA representative approve a detention order. As defined in proposed § 1.377, an "authorized FDA representative" is ~~defined as~~ an FDA District Director in whose district the detained article of food is located or an FDA official senior to such director. A Regional Food and Drug Director is an FDA official senior to an FDA District Director. This is consistent with the approval requirements found in section 303 of the Bioterrorism Act. We are proposing that if prior written approval of a detention order is not feasible, prior oral approval must be obtained and confirmed in writing as soon as possible. We believe allowing for oral approval of a detention followed by written confirmation allows for efficient implementation of the administrative detention provisions.

For example, the investigator may be at a manufacturing plant located a great distance away from the district office and may determine that a detention is warranted. Instead of losing

valuable time driving back to the district office to get a written signature in cases where a fax machine is not close by, the investigator may telephone the authorized FDA representative to get an oral approval. The authorized FDA representative would subsequently confirm the oral approval in writing by sending written confirmation to the investigator. In other circumstances where there is risk of the product moving to another location, we would want to detain the product immediately and an oral approval of the detention order may be prudent, followed by confirmation in writing. These examples illustrate some situations where oral approval may be necessary, but do not constitute an all inclusive list.

2. Who receives a copy of the detention order? (Proposed § 1.392)

Proposed § 1.392(a) requires FDA to issue the detention order to the owner, operator, or agent in charge of the place where the article of food is located. If the owner of the article of food is different from the owner, operator, or agent in charge of the location of the food, FDA must provide a copy of the detention order to the owner of the article of food if the owner's identity can be determined readily.

Proposed § 1.392(b) would subject common carriers of

articles of food to these administrative detention provisions. If FDA issues a detention order for an article of food located in a vehicle or other carrier used to transport the detained article of food, FDA would be required to provide a copy of the detention order to the shipper of record and the owner and operator of the vehicle or other carrier, if FDA can determine their identities readily.

3. What information must FDA include in the detention order? (Proposed § 1.393)

Proposed § 1.393(a) requires FDA to issue the detention order in writing, signed and dated by the officer or qualified employee of FDA who has credible evidence or information indicating that such article of food presents a threat of serious adverse health consequences or death to humans or animals. The written detention order serves as notice of the detention and provides notice that the persons with ownership rights to the detained article of food have the right to request an informal hearing.

Proposed § 1.393(b) requires the detention order to include the following information:

1. The detention order number;

2. The date and hour of the detention order;
3. Identification of the detained article of food;
4. The period of the detention;
5. A statement that the article of food identified in the order is detained for the period shown;
6. A brief, general statement of the reasons for the detention;
7. The address and location where the article of food is to be detained and the appropriate storage conditions;
8. Any applicable conditions of transportation of the detained article of food;
9. A statement that the article of food is not to be consumed, moved, altered, or tampered with in any manner during the detention period, unless subject to a limited conditional release under proposed § 1.381;
10. The text of section 304(h) of the act and §§ 1.401 and 1.402 of this chapter;
11. A statement that any informal hearing on an appeal of a detention order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in proposed § 1.403;
12. The mailing address, telephone number, email address, and fax number of the FDA district office and the name of

the FDA District Director in whose district the detained article of food is located; and

13. A statement indicating the manner in which approval of the detention order was obtained, i.e., orally or in writing.

D. What is the appeal process for a detention order?

1. Who is entitled to appeal? (Proposed § 1.401)

Under proposed § 1.401, any person who would be entitled to be a claimant for such article of food, if seized under section 304(a) of the act, would be able to appeal a detention order. Procedures for establishing entitlement to be a claimant for purposes of section 304(a) of the act are governed by Supplemental Rule C(6)(a) to the Federal Rules of Civil Procedure.

2. What are the requirements for submitting an appeal? (Proposed § 1.402)

Proposed § 1.402 describes the requirements for submitting an appeal. As required by section 303 of the Bioterrorism Act, as part of your appeal, you may request an opportunity for an informal hearing. Proposed § 1.402(a) will require you to submit

your appeal in writing to the FDA District Director in whose district the detained article of food is located using the contact information provided in the detention order. We propose to allow you to submit your appeal by mail, email, or fax.

The timeframe for filing an appeal is determined by whether the detained article of food is perishable or non-perishable. If the detained article of food is perishable, as defined in proposed § 1.377, you would be required to file your appeal and request for a hearing within two calendar days of receipt of the detention order.

If the article of food subject to the detention order is non-perishable, you would be required to file a notice of intent to request a hearing within four calendar days of receipt of the detention order. The notice of intent would enable the agency to determine whether resources should be allocated to preparing for a regulatory hearing. If you do not file a notice of intent by day four, you do not receive a hearing. However, without filing a notice of intent by day four, you may still file an appeal without a hearing request. Whether or not you are requesting a hearing, your appeal involving a detained non-perishable food must be filed within ten calendar days of receipt of the detention order.

We are using calendar days for the bifurcated deadlines for

filing appeals to provide the most expeditious procedure for perishable food, and to provide a consistent approach for counting days. We are asking for comment on whether there are other ways we should be counting days for filing appeals, while adhering to the statutory deadline of five days for FDA to issue a decision on appeal (for both perishable and non-perishable food).

Proposed §1.402(b) provides that your request for an appeal must include a verified statement identifying your ownership or proprietary interest in the detained article of food. Under Federal Rules of Civil Procedure, Supplemental Rule C(6)(a), a person who asserts an interest in or right against property that is the subject of an action must file a verified statement identifying the interest or right. The meaning of "verified statement" under Rule C(6)(a) is governed by the local federal district court rules in which the detention takes place, and usually means that the statement must be accompanied by an oath or affirmation attesting to the statement's veracity.

Proposed § 1.402(c) provides that the appeal process would terminate if FDA institutes either a seizure action under section 304(a) of the act or an injunction under section 302 of the act regarding the detained article of food.

Proposed § 1.402(d) describes the requirements for

requesting an informal hearing as part of the appeals process. Your request for a hearing must be in writing and be included with your appeal. You may appeal a detention without requesting an informal hearing; however, if you want an informal hearing, you must include your request when you file your appeal. This proposed section describes the timeframes for holding the hearing if FDA grants your request for an informal hearing (see 21 CFR 16.26 regarding denial of hearing). If the detained article of food is perishable, the hearing would be held within two calendar days after the date the appeal is filed. If the detained article of food is non-perishable, the hearing would be held within three calendar days after the date the appeal is filed. The quick timeframes for holding the hearing are necessary to ensure that FDA can adhere to the statutory requirement to issue a decision on appeal within five days after the appeal is filed. FDA notes that under this proposal, the timeframes for perishable and non-perishable appeals will not be significantly different in instances where an appeal is filed immediately upon receipt of a detention order. For example, if you file an appeal and request for a hearing on the same day (day one) the detention is ordered for a perishable food, the hearing would be held by day three, and the decision on appeal could be issued as early as day three but no later than day six. If a non-perishable food was detained

in the same example, the hearing would be held by day four, and the decision on appeal could be issued as early as day four but no later than day six.

We are requesting comment on the timeframes for holding the informal hearing.

3. What requirements apply to an informal hearing? (Proposed § 1.403)

If FDA grants a request for an informal hearing on an appeal of a detention order, FDA would conduct the hearing in accordance with 21 CFR part 16, with the following exceptions:

- The detention order under proposed § 1.393, rather than the notice under § 16.22(a) of this chapter, would provide notice of opportunity for a hearing under this section and would be part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.
- A request for a hearing under this section must be addressed to the FDA District Director in whose district the detained article of food is located in accordance with proposed § 1.402(a).
- The provision in § 16.22(b) of this chapter, providing that a person not be given less than three (3) working days after receipt of notice to request a hearing, does not apply to a

hearing under this subpart. Rather, the timeframes in proposed § 1.402(a) apply.

- The provision in § 16.24(e) of this chapter, stating that a hearing may not be required to be held at a time less than two (2) working days after receipt of the request for a hearing, does not apply to a hearing under this subpart. Instead, the timeframes in proposed § 1.402(c) apply.
- Proposed §1.406, rather than § 16.24(f) of this chapter, describes the statement that will be provided to an appellant where a detention order is based on classified information.
- Proposed § 1.404, rather than § 16.42(a) of this chapter, describes the FDA employees, i.e., regional food and drug directors or other officials senior to District Directors, who preside at hearings under this subpart.
- Under proposed § 1.403(f), the presiding officer may require that a hearing conducted under this section be completed within one day, as appropriate.
- Ordinarily under part 16 hearing procedures, the presiding officer issues a report and recommended decision and the Commissioner issues a final decision. However, under proposed § 1.403(g), the presiding officer will issue the

final agency decision.

As described previously, the informal hearing requirements in 21 CFR part 16 state that its procedures are to be used when the act or FDA regulations provide for an opportunity for a hearing and no specific hearing regulations exist (see 21 CFR 16.1(b)). Section 303 of the Bioterrorism Act provides for an informal hearing opportunity, but does not provide specific provisions for the informal hearing. In this proposed rule, we are applying part 16 procedures modified by the noted exceptions, which is consistent with 21 CFR 16.5(b).

4. Who serves as the presiding officer at an informal hearing? (Proposed § 1.404)

Proposed § 1.404 requires the FDA Regional Food and Drug Director (RFDD), or other official senior to a District Director, to act as the presiding officer of an informal hearing on an appeal of a detention order. As presiding officer, the RFDD would issue the decision on appeal. Because a detention must be approved at the District Director level, we believe it is appropriate that appeals of those decisions should be handled by persons in positions senior to the District Directors.

The presiding officer may be an RFDD from a region other than the one in which the detained article of food is located, or

another official senior to a District Director.

5. When does FDA have to issue a decision on an appeal? (Proposed § 1.405)

Proposed § 1.405 describes when FDA must issue a decision on an appeal. Proposed § 1.405(a) requires the presiding officer to issue a decision confirming or revoking the detention order within five calendar days after the appeal is filed. If FDA fails to provide an opportunity for a hearing, or fails to confirm or terminate the detention order within the five day period, the detention order is deemed terminated. While the Bioterrorism Act does not define the meaning of "an opportunity for an informal hearing," we interpret this phrase to mean the FDA gives notice of the opportunity~~right~~ for ~~to~~ a hearing (see also proposed § 1.403(a), which states that ~~states~~ the detention order provides notice of opportunity for a hearing). Under this interpretation~~, i.e.~~, a failure to provide an opportunity for a hearing means a failure to provide you with notice of your opportunity to request a hearing. This provision is consistent with requirements of section 303 of the Bioterrorism Act.

Proposed § 1.405(b) would allow you to appeal the detention order without a request for an informal hearing. Where you appeal without requesting a hearing, the presiding officer is

still required to issue a decision on the appeal confirming or revoking the detention within five calendar days after the date the appeal is filed. If the presiding officer fails to issue a decision within the five day period, the detention order is deemed terminated.

Proposed § 1.405(c) states that if you appeal a detention order and request an informal hearing and your hearing request is denied, the presiding officer is still required to issue a decision on the appeal confirming or revoking the detention within five calendar days after the date the appeal is filed. If the presiding officer fails to issue a decision within the five day period, the detention order is deemed terminated.

Proposed § 1.405(d) states if the presiding officer confirms a detention order, the article of food would continue to be detained until FDA terminates the detention order under proposed § 1.384 or the detention period expires under proposed § 1.379, whichever occurs first.

Proposed § 1.405(e) states that if the presiding officer terminates a detention order, or the detention period expires, FDA would be required to terminate the detention order as specified under proposed § 1.384 (i.e., FDA would be required to issue a detention termination notice releasing the article of food).

Proposed § 1.405(f) states that confirmation of a detention order by the presiding officer is considered a final agency action for purposes of section 702 of title 5, United States Code (5 U.S.C. 702).

6. How will FDA handle classified information in an informal hearing? (Proposed § 1.406)

FDA expects that consistent with responding to bioterrorist threats, there may be instances where the credible evidence or information supporting a detention order consists of Classified National Security Information ("classified information"). Protection of information critical to our nation's security is a priority (Executive Order 12958, April 17, 1995). While mindful of our duty to protect our national security interest, we are also mindful of our obligation to provide a fair, expeditious, and impartial hearing (see 21 CFR 16.60 regarding hearing procedure). Proposed § 1.406 provides that FDA will not release classified information. However, if the presiding officer may do so, consistent with safeguarding both the information and the source, the presiding officer will give you notice of the general nature of the information and an opportunity to offer opposing evidence or information. If classified information was used to support the detention, then any confirmation of such detention

will state whether it is based in whole or in part on that classified information.

Given the events of September 11, 2001 and the need to quickly respond to actual or threatened bioterrorist attacks, we are contemplating the development of general regulations that address handling classified information on an agency-wide basis for all the products regulated by FDA. We believe, though, that we should go forward with the current proposal in this context at this time.

IV. Conforming Amendment to 21 CFR part 16

We propose to amend § 16.1(b)(1) (21 CFR 16.1(b)(1)) to include section 304(h) of the act relating to the administrative detention of food for human or animal consumption to the list of statutory provisions under which regulatory hearings are available.

V. Analysis of Economic Impact

A. Benefit-Cost Analysis

FDA has examined the economic implications of this proposed rule as required by Executive Order 12866. Executive Order 12866 (EO 12866) directs agencies to assess all costs and benefits of

available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). EO 12866 classifies a rule as a significant regulatory action if it meets any one of a number of specified conditions, including: having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. EO 12866 also considers a regulatory action significant if it raises novel legal or policy issues. ~~. We have determined that this proposed rule is not a significant regulatory action as defined by EO 12866.~~ The Office of Management and Budget has determined that this proposed rule is a significant regulatory action under Executive Order 12866, although it is not economically significant.

Need for Regulation

Section 303 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act" or "the Act") (PL107-188), gives FDA expanded authority to prevent the distribution of any article of food for which we have

credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals. Previously, if we received credible evidence or information indicating that an article of food presented a threat of serious adverse health consequences or death to humans or animals, we would typically have taken one of the following actions: (1) requested a voluntary recall of the suspected product; ~~or~~ (2) developed enough evidence to move directly to seize ~~the food; or (3) provided information to the states and asked them to investigate and to use their authority to embargo~~ the food; or (3) referred the ~~problem~~ matter to the appropriate state authority for most cases involving purely intrastate commerce. Thus, Congress' expansion of our authority to allow administrative detention of food permits us to immediately detain food in commerce, which provides an added measure to ensure the safety of the nation's food supply.

Reason for Regulation

FDA is proposing this regulation to improve food safety. Food safety is mostly a private good. Establishments have powerful incentives to ensure that the ingredients they purchase are not contaminated and that their production processes are

protected from unintentional and intentional contamination. Deliberate (intentional) contamination of food linked to a particular product or plant - particularly if the plant is considered negligent - would be extraordinarily costly to a firm. Indeed, the private incentives to avoid deliberate contamination should be similar to the private incentives for food safety. Deliberate food contamination events nonetheless differ from ordinary outbreaks of food-borne illness in that they are more likely to be low probability events with severe public health consequences.

Although private incentives lead to the private efforts to protect against deliberate contamination at the plant level, there are external effects associated with privately produced protection. The economic incentives for firms to engage in food safety activities largely hinges on the ability of consumers to identify and avoid products associated with the responsible party. However, firms can change both their own names and the names of their products, and can also change owners and managers. Therefore, it may be quite costly for consumers to obtain the information that would allow them to avoid products associated with the responsible party. Moreover, some firms might be ~~formed specifically as a platform from which~~ infiltrated by those who wish to launch attacks on food safety, or might even have been

formed by those having that end in mind. Such firms would not be responsive to normal economic incentives to provide food safety.

The events of September 11, 2001, led Congress to conclude that there should be a regulatory mechanism to temporarily remove from commerce potentially violative food that presents a threat of serious adverse health consequences or death to humans or animals, and store it under an appropriate level of security until we can investigate the potential threat and evaluate whether to initiate judicial enforcement action and, if appropriate, initiate such action. This proposed regulation implements this mechanism.

Regulatory Options

We considered several regulatory options or alternatives in developing this proposal:

Option One, establish a regulatory framework for administratively detaining food, with expedited procedures for instituting certain enforcement actions involving perishable food (i.e. take the proposed action);

Option Two, take the proposed action, but change the definition

of perishable food, the maximum time frame for administrative detention of perishable food, or both;

Option Three, take the proposed action, but define the level of security we require for transportation and storage;

Option Four, promulgate regulations only to establish expedited procedures for instituting certain enforcement actions involving perishable food (i.e. limit the action to the regulations required by section 303 of the Bioterrorism Act).

We request comments on these options, as well as suggestions on other regulatory options that we should consider. We will address comments on this analysis in the analysis of the final rule.

Baseline: The situation before Congress passed the Public Health Security and Bioterrorism Preparedness And Response Act Of 2002 (the Bioterrorism Act)

Usually, we designate the option of taking no regulatory action as the baseline. ~~In that case, w~~We then compare the costs and benefits of the various regulatory options to the current

regulatory state of affairs. However, for this rule, we chose the situation that existed before Congress enacted the Bioterrorism Act as the baseline. We chose this baseline rather than the current regulatory state of affairs because our authority to administratively ~~, because the authority to~~ detain food ~~exists~~ under the Bioterrorism Act already exists, regardless of whether we now promulgate regulations setting out the procedures we will follow when we detain food. ~~We choose this baseline because we wished to analyze the impacts of our authority to administratively detain food, which Congress granted to us under the Bioterrorism Act. Therefore, we specified a baseline that predates our receiving that authority. In this analysis, we do not discuss the option of taking no regulatory action. Option Four (establish expedited enforcement actions involving perishable food only) most closely resembles the option of taking no regulatory action, because in that option we would limit ourselves to only the regulatory action that Congress required us to take in the Bioterrorism Act. By convention, we do not attribute costs or benefits to the baseline, per se, but instead capture the impacts of the regulation by comparing the costs and benefits of the other options to the baseline.~~

Therefore, in order to analyze the impact of Congress giving us the authority to administratively detain food, we needed to

specify a baseline that predated our having received that authority. By convention, we do not attribute costs or benefits to the baseline, per se, but instead capture the impacts of the regulation by comparing the costs and benefits of the other options to the baseline. Prior to Congress passing the Bioterrorism Act, we had other enforcement options available to us in those situations in which we can now use administrative detention~~authority~~, that is, in which we receive credible evidence or information that an article of food presents a threat of serious adverse health consequences or death to humans or animals. We will discuss those enforcement actions as part of the baseline in the following analysis.

In addition, we do not discuss the option of taking no regulatory action as one of the non-baseline options, because that option is not legally feasible. Option Four (establish expedited procedures for instituting certain enforcement actions involving perishable food only) most closely resembles the option of taking no regulatory action, because in that option we would limit ourselves to only the regulatory action that Congress required us to take in the Bioterrorism Act.

Option One: Establish a regulatory framework for administratively detaining food, with expedited procedures for instituting certain enforcement actions involving perishable food (i.e. take the proposed action)

In the proposed action, we establish a regulatory framework for administratively detaining food.

Costs

The primary costs of the proposed rule arise from differences between administrative detention and other enforcement actions with respect to the following: 1) cost of transporting and storing food, if necessary; 2) cost of canceling previously scheduled transportation and storage of the affected food when we remove it from commerce, and rescheduling transportation and storage if we later cancel the detention order and release it back into commerce; 3) loss of product value over the detention period, if we later find the food is not violative; and 4) cost of participating in appeals hearings and other enforcement activity.

To analyze the costs of the proposed rule, we first estimate how many times we might use administrative detention. We then estimate the proportion of cases in which we might

administratively detain food that we later determine to be not violative. We need to estimate this percentage because we estimate the loss of product value over the detention period for food that we later find to be not violative. (We do not estimate the loss of product value for violative food, because we assume that the violation, not our action, reduces the value of that food.) We then estimate how costs would change if we substituted an administrative detention action for other enforcement actions. We look at the change in costs relative to the baseline of taking these other actions because we probably would have taken some type of enforcement action if we had received the type of information that would allow us to use administrative detention. In other words, we analyze the cost of administrative detention actions in terms of the costs over and above those that would have been associated with the enforcement actions that we would otherwise have taken. We then multiply the changes in costs by the number of times we might substitute an administrative detention action for the other enforcement actions.

Estimate of Number of Times We Might Use Administrative Detention Per Year

We do not know how often we will receive credible evidence

or information that an article of food presents a threat of serious adverse health consequences or death to humans or animals that would allow us to administratively detain food~~; nor do we know the number of times we would choose administrative detention over issuing a Class I recall request or moving directly to institute a seizure action against the food ("seize" or "move directly to seize" for purposes of this analysis), even if we had that type of information. Therefore, we base our estimate of the number of times per year that we might use administrative detention on the number of the times per year that we have issued Class I recall requests, and the number of times we moved directly (i.e. with no preliminary enforcement action, such as state embargo) to seize food presenting health or safety problems~~. However, if we had received credible evidence or information that an article of food presented a threat of serious adverse health consequences or death to humans or animals before Congress granted us authority to take administrative detention actions, we would probably have taken one of the following three ~~two~~ actions: (1) requested a voluntary recall of the suspected product; (2) moved directly to seize the food; or (3) referred the ~~problem~~ matter to state authorities. We specify moving directly to seize food because we could also seize food after taking some other enforcement action, including

administrative detentions. To avoid having to describe streams of enforcement actions, we have simplified the situation into two phases, a "preliminary phase," in which we take some action to detain the food in order to investigate it, and a "final phase" in which we take some final action such as seizing the food or referring the ~~problem~~ matter to state authorities. ~~We assume that if we had the type of information that would allow us to use administrative detention, then we would have moved directly to the final phase of seizing the food.~~

We base our estimate on only these three~~two enforcement~~ actions because we believe the situations that lead to these types of actions are the most similar to the situations that may lead to administrative detention. Thus, we assume that any administrative detention would replace ~~either~~ issuing Class I recalls, ~~or~~ moving directly to seizure, or referring the ~~problem~~ matter to state authorities for most cases involving purely intrastate commerce. If we instead assumed that we might substitute administrative detention actions for other types of enforcement actions, including other actions that we subsequently follow with seizure actions, then our estimate of the number of administrative detentions per year could be significantly larger. Examples of other types of enforcement actions include detentions without physical examination (DWPE) and requests to

states to embargo food. We assume~~estimate~~ that the number of administrative detentions might include ~~be~~ 0 to 100 percent of the number of class I recalls and instances in which we moved directly to seize food, and 0 to 10 percent of the number of times we referred ~~problems~~ matters to state authorities. In all cases, we based the low end of the range on the fact that we do not know if we would have used administrative detention, even if we had the authority to do so, and the criteria for using administrative detention had been met. Analyzing all the factors that would lead us to choose one enforcement action over another is beyond the scope of this analysis. We choose 100 percent as the high end of the range for class I recalls because the criteria for class I recalls is quite similar to the criteria for administrative detention. We chose 100 percent as the high end of the range for instances in which we move directly to seize~~ure~~ food as a practical expedient because the small number of actions implies that such information would have had little or no impact on our cost estimates. We chose 10 percent as the high end of the range for state referrals based on our experience with those ~~enforcement~~ actions. ~~and instances in which we move directly to seize food, because we do not know the proportion of those actions that involved the type of information that would have allowed us to use administrative detention, and we also do not~~

~~know if we would have used administrative detention rather than one of those enforcement actions, even if we had the requisite level of information.~~ ~~An analysis of all the factors that would lead us to choose one enforcement action over another is beyond the scope of this analysis.~~

In fiscal year 2002, we initiated 184 Class I recalls involving food that posed a risk of serious adverse health consequences or death to humans or animals. In the same year, we initiated 16 seizures that may have involved food products that posed hazards to human or animal health. In the last ~~twelve~~ 12 months, we estimate that we referred 234 of such matters ~~problems~~ to state authorities.

These numbers are repeated in Table 1 of this document. Based on this information, we estimate that we might administratively detain food ~~approximately~~ 0 to 223~~200~~ times per year.

Table 1 - Substitutions per year	
Action	**Estimated Number of Substitutions of Administrative Detention for Other Enforcement Actions per Year**
Class I recalls	0 to 184
No preliminary action (move	0 to 16

directly to seizure)	
No preliminary action (refer ~~problem~~ matter to state authorities)	0 to 23
Total	0 to 223~~200~~

Estimate of the proportion of cases in which the food subject to administrative detention turns out to be not violative

Some of the costs that we will discuss later are only relevant if we eventually determine that food that we have administratively detained is actually not violative. We do not know the proportion of cases in which we might administratively detain food that we later determine to be not violative. This rate depends on the type of information we receive, and the level of risk aversion we adopt when we apply the criteria allowing us to use administrative detentions, including "credible evidence or information" and "threat of serious adverse health consequences or death to humans or animals." If we only administratively detain food when we are certain or nearly certain that it is violative, then we may eliminate administrative detention as an enforcement option for some food that is violative. However, if we administratively detain food when we are less certain that it is violative, then we will increase the rate at which we

administratively detain food that we later determine is not violative.

One way of addressing the proportion of cases in which we might administratively detain food that we later determine to be not violative is to look at data from the detention and release of imported food. However, this data cannot be narrowed to situations where we have detained or prepared to detain food and then later determined that the food was not violative. An import detention is different from administrative detention in that imports can be detained for reasons other than adulteration or misbranding. These other reasons give rise to a large percentage of detentions in which the food is found not to be violative. For instance, an import can be detained because the product is coded in the OASIS (Operational and Administrative System for Import Support system) system as a low acid canned food (LACF) but the importer did not supply the food canning establishment (FCE) number. The OASIS system is a national database on imports, and related enforcement activities and findings.

In the first three quarters of 2002, we released 48 percent of the shipments of human and animal food that we detained, excluding the shipments that we released because the firm reconditioned the food. The percentage of import shipments released includes all releases recorded in the OASIS system.

These data include releases from detentions resulting from:

- DWPE notices,
- routine FDA field sampling assignments,
- incorrect or incomplete information provided about the product, and
- imports released with comment, which means the product technically is misbranded or adulterated but we exercise enforcement discretion.

Because of the factors listed above, and because import detentions may be based on a lower level of information than that required for an administrative detention, we cannot directly impose these numbers on administrative detentions. Rather, 48 percent is an upper limit that will exceed the non-violative percentage of administratively detained food.

Another way of addressing this issue is to look at the proportion of enforcement actions against non-food products that involved products that we later determined were not violative. We have had authority to administratively detain medical devices since 1976. During that time, we have not administratively detained any products that we later found to be not violative. This suggests that the rate at which we administratively detain food that is not violative may also be quite low, because in both cases we would be using similar administrative detention

procedures. However, the medical device and food contexts may differ with respect to a number of potentially relevant issues, such as the type and amount of products on the market, the types of problems associated with those products, and the type and level of information that we receive on those problems.

Based on this information, we estimate that 0 to 48 percent of the food that we administratively detain will later turn out to be not violative.

Transportation

Under the proposed rule, we might require ~~firms having control of~~ a firm to transport food that we administratively detain to ~~transport the food to secure facilities that provide proper storage conditions for~~ a storage facility that is both secure and capable of providing the proper conditions for storing that type of food. In other cases, we might allow firms to hold the food in place, but require them to take various other actions to secure the food, such as physically segregating it, locking the area in which they store it, and possibly posting guards to monitor the area in which they store it. We will determine whether or not to require a firm to transport administratively detained food to another storage facility, and to take other

actions to secure that food, on a case-by-case basis.

An example of where transporting detained food ~~this type of decision~~ might be problematic would be the case of large storage grain bins located at private elevators and farms that hold grain. These bins typically hold several hundred tons per bin. It would be costly to transport grain to another holding area. In addition, transporting contaminated grain might spread biological or chemical agents because of the generation and dispersal of dust from the grain as we remove it from the bin and transport it to another location. In this case, it could be preferable to allow the product to be stored in place, possibly with the addition of on-site security.

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We do not have sufficiently detailed information on past enforcement actions to estimate the proportion of administrative detentions in which we might require transportation or any other activity. Therefore, we assume that we would require firms to transport food to a secure facility and store them there in 0 to 100 percent of administrative detention actions. To simplify the analysis, we tentatively assume that the estimated costs of transporting food to a secure facility and storing it there are equal to or greater than the costs of storing the food in place and taking any of the other actions that we might require under our administrative detention authority, except posting additional

guards, which we analyze in the discussion of Option Three (take the proposed action, but define the level of security we require for transportation and storage). As we discuss in the section on Option Three, the estimated cost of providing one additional security guard for on-site storage is somewhat higher than the estimated cost of transporting food to a secure facility. Therefore, we have not discussed the cost of providing an additional security guard as part of this option. Nevertheless, providing an additional security guard and storing food in place is consistent with taking the proposed action, and we may take that action in some cases.

The cost of transporting food varies along a number of dimensions, including the following: 1) type of conveyance used; 2) distance traveled; 3) level of security; 4) type and amount of food involved; and 5) number of trips required. These considerations are interrelated. For example, the appropriate type of conveyance might depend on the level of security, the distance to be traveled, and the amount of food involved. Similarly, the distance to be traveled would depend, in part, on what type of facility meets our security requirements.

Firms may transport food via truck, rail, air, or ship. Based on the distance to be traveled, the level of security we might require, and the type and amount of food involved, we

tentatively assume that firms would usually move administratively detained food by truck.

We also assume that when we require firms to transport food to a "secure storage facility," we will usually interpret that term to mean a bonded or third party public warehouse. We assume that these warehouses would provide proper storage conditions to maintain the safety and wholesomeness of the food. Bonded warehouses, refrigerated warehouses, and most types of third-party public warehouse facilities are readily available around ports of entry into the United States. Most metropolitan areas have an international airport that serves as a port of entry into the United States, and will, therefore, have a variety of warehouses available. Therefore, we assume that the distance that we would require firms to transport administratively detained food would normally be no farther than the distance to the nearest metropolitan area. Firms might undergo additional transportation costs if we later cancel the administrative detention order and release the food back into commerce, because the secure facility might not be as convenient to the subsequent destination as the original location. Therefore, we calculate the transportation costs associated with food that we later release on the basis of round trip travel between its original location and the secure storage facility. ~~We request comments on~~

~~the availability and location of suitable secure storage facilities and the assumptions we make concerning distances.~~

Transportation costs would depend, in part, on the security measures that we direct firms to take. We do not define those measures in this proposed rule. Instead, we will determine the relevant level of security and types of security measures needed on a case-by-case basis. We tentatively assume that a normal or average level of security for transportation of food would be the level associated with bonded or third party carriers. We believe using these types of carriers rather than a firm's own transportation system could provide some additional security because the owner of the bonded or third-party carrier might have a greater financial incentive to monitor and maintain custody of the food than do the owners of the food. In some cases, we might require higher security. In other cases, we might require lower security, such as that associated with a firm's own transportation system.

The cost of transporting food varies widely with the type and quantity of food. Some food requires specialized trucks, such as bulk liquid or refrigerated carriers. We base our estimate of the average transportation costs on the average rates for transporting the "most usual loads" of various fresh fruits and vegetables as reported in the Agricultural Marketing

Service's Fruit and Vegetable Truck Rate Report for the week ending November 19, 2002. (Ref. 1). These loads of fresh fruits and vegetables do not require specialized trucks. We think that average transportation costs should be similar because the proportion of food that requires specialized trucks is relatively small. However, we request comment on this assumption, and on the cost of specialized transportation. ~~The truck report listed a number of common origins and destinations. We choose a variety of origins and destinations that we thought might reflect the average distances from any point in the U.S. to nearest a major metropolitan area, i.e., we excluded longer, cross-country trips, and shorter, local trips.~~ We assume ~~that firms~~ there would be ~~able to find~~ suitable ~~secure~~ storage facilities in the nearest major metropolitan area. ~~The range of costs for ten medium distance one-way trips for a variety of different types of produce in different parts of the U.S. was $1,700 to $2,000. We list the trip origin and destinations that we used to arrive at these estimates in Table 2. We request comments on these assumptions.~~ However, we do not know the average distance from any randomly chosen point in the United States to the nearest metropolitan area. Therefore, we tentatively assume that the distance from any location at which we might detain food to the nearest metropolitan area would be between 30 and 200 miles. Most of the

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trips in the trucking report were much longer than 200 miles. However, the report listed ~~ten~~ 10 trips under 300 miles. The trucking report included both a low cost and a high cost estimate. Using these estimates gives an average cost per mile for the ~~ten~~ 10 trips under 300 miles of between $4.26 and $5.13. The actual cost per mile varied from a high of $23.91 for the high cost estimate for the shortest trip (23 miles) to $1.93 per mile for the low estimate for an intermediate length trip (243 miles). Costs per mile are higher for shorter trips because some costs are probably fixed and do not increase with mileage. We use the range for the average cost per mile for all trips under 300 miles because we have insufficient information to estimate a distribution of trips by distance. Based on this assumption, we estimate that the average transportation cost per truckload will be between approximately $100 and $1,000.

~~**Table 2 – Origins and Destinations for Medium Length Trips Used to Estimate Cost of Travel to a Metropolitan Area**~~

~~**Origin**~~	~~**Destination**~~
~~Central and Western AZ~~	~~Dallas~~
~~Nogales AZ~~	~~Dallas~~
~~South District, CA~~	~~Dallas~~

~~South District, CA~~	~~Denver~~
~~Central San Joaquin Valley, CA~~	~~Dallas~~
~~Central San Joaquin Valley, CA~~	~~Denver~~
~~San Joaquin Valley, CA~~	~~Dallas~~
~~San Joaquin Valley, CA~~	~~Denver~~
~~Idaho and Malheur County, OR~~	~~Chicago~~
~~Upper Valley, ID~~	~~Chicago~~
~~Maine~~	~~NYC~~

In order to use these transportation rates, we need to know the average amount of food that we would administratively detain. The amount of food that we administratively detain could be anything from a few packages, to a lot, a shipment, or a production run. The amount of food involved in Class I recalls and seizure actions has ranged from one hundred pounds or less, in the case of some seizure actions, to millions of pounds, in the case of some Class I recalls. Therefore, we estimate that we will administratively detain between 0 and 1 million pounds of food per administrative detention. We request comments on this assumption.

To apply the information on transportation costs, which was based on the most usual load of produce (as defined by the Agricultural Marketing Service's Fruit and Vegetable Truck Rate Report), to our assumption about the amount of food that we might administratively detain, which we expressed in pounds, we need to estimate the average weight in pounds of the most usual loads of produce. One way to do this is to look at the average weight of

lines of imported produce, and to assume that the size of an average line of produce is comparable to the size of the most usual load of produce. A line in this context is the unit by which we record information on imported food; it does not refer to a product line. We base the assumption relating the size of the line of produce to the most usual load of produce on the fact that most imported produce arrives by truck, so that the typical unit of imported produce probably corresponds roughly to a usual truckload of that produce. We request comments on this assumption.

In 2001, firms imported approximately 22.6 billion pounds of forty-eight common types of fresh produce into the United States. (Ref. 4) We extrapolated data on the number of lines in the OASIS database for the first three quarters of FY2002 for all product categories that appear relevant to fresh produce to estimate that the total number of lines will be approximately 1.5 million by the end of fiscal year 2002. If the amount of imports in 2001 were similar to that for fiscal year 2002, then the average line would be about 15,000 pounds. Therefore, we assume that the most usual load of produce would be about the same size as the average line of imported produce, or 15,000 pounds. We have insufficient information to estimate the weight of the average line for any other type of food. Therefore, we assume

that the average truckload across all types of food is about 15,000 pounds. Under this assumption, each administrative detention may involve transporting approximately 0 to 67 truckloads of food.

Additional transportation costs might arise if we conditionally released food that we administratively detained, and firms moved the conditionally released food to another location. We have not included these costs because of the voluntary nature of these limited conditional releases. A firm would not request a limited conditional release unless the benefits of doing so outweighed the costs. Therefore, any increase in transportation costs would be at least offset by some form of cost savings. If we were to analyze the impact of the availability of these limited conditional releases, then our estimate of the costs associated with this proposed rule would be somewhat lower. However, the impact would probably be small, because we do not expect many requests for limited conditional release.

We request comments on all assumptions relating to transportation costs, including but not limited to the average amount of food that we might administratively detain, the average amount of food per truck load or per load of other conveyance, the likelihood that firms will use different types of conveyances

(i.e. trucks, airplanes, trains, and ships), ~~and~~ the costs of using various types of specialized conveyances, and the distances that firms may need to transport food.

As explained earlier in this analysis, we are analyzing the cost of administrative detention actions relative to the baseline of taking the enforcement actions we would have taken prior to having received authority to take administrative detention actions. Therefore, only the costs that go beyond the costs of those other enforcement actions are relevant here. We assume there would be no change in transportation costs if we substituted an administrative detention action for a Class I recall, because firms probably already transport food as part of such a recall.

We ~~include~~considered the costs of transportation under Class I recalls to be part of the baseline costs, even though such recalls are voluntary, because we have some influence over those decisions. We have influence over those decisions because we could publicize the fact that we requested a firm to recall a product, which might have consequences for that firm's profits. Therefore, those decisions are not purely private market decisions. As such, ~~and~~ it is reasonable to classify the costs associated with those recalls as social costs that are comparable to the social costs associated with administrative detention

actions for purposes of determining baseline costs. If we did not treat these costs as social costs, then substituting administrative detention for Class I recalls would generate additional social costs related to transporting food.

Moving directly to a seizure action or referring a ~~problem~~ matter to state authorities does not involve any transportation costs prior to the seizure action or referral. Therefore, all transportation costs associated with an administrative detention are relevant in the case of an administrative detention that replaces a case of moving directly to a seizure action or a referral to state authorities. Any transportation costs associated with the actual seizure or state action would not be relevant in this context, because administrative detentions may be followed by seizure actions or state actions, so any transport~~i~~ration associated with the seizure action or state action would take place irrespective of whether it was preceded by an administrative detention or not.

We present transportation costs in Table ~~3~~2 of this document. We calculated these figures by multiplying the number of truckloads that ~~may~~we estimated would be involved in an administrative detention (0 to 67) by the number of times we might ~~replace~~ use administrative detention ~~for~~ in place of Class I recall requests, ~~or~~ cases of moving directly to seizure, or referring a matter to state

authorities. ~~We calculated the number of round trips by multiplying the number of one way trips times the estimated percentage of cases in which we might release a detention order and allow food back into commerce.~~The number of one way trips includes return trips, which we calculated by multiplying the number of trips to secure storage facilities by the estimated percentage of cases in which we might terminate a detention order and allow food back into commerce (0% to 48%). Again, estimated costs are higher for administrative actions that replace cases of moving directly to seizure actions or referring matters~~problems~~ to states than for administrative actions that replace class I recalls because we are using the costs of those other actions as the baseline, and class I recalls already involve transportation, while cases of moving directly to seizure actions or referring ~~problems~~ matters to states do not.

~~Table 3 – Annual Transportation Costs~~				
~~Action Replaced by Administrative~~	~~Additional One Way Trips per Year Due~~	~~Additional Two Way Trips per Year Due~~	~~Cost per Trip, each way~~	~~Total Transportation Cost (in millions)~~

~~Detention~~	~~to Substitution, in Truckloads~~	~~to Substitution~~		
~~No preliminary action (move directly to seizure)~~	~~0 to 1,067~~	~~0 to 512~~	~~$1,700 to $2,000~~	~~$0 M to $3 M~~
~~Class I recalls~~	~~0~~	~~0~~	~~$1,700 to $2,000~~	~~$0~~
~~Total~~				~~$0 M to $3 M~~

Table 2 - Annual Transportation Costs				
Action	**Number of Actions**	**Additional One Way Trips per Year, in Truckloads**	**Cost per One Way Trip**	**Total Transportation Cost (in millions)**
Administrative Detention	0 to 16	0 to 1,587	$1,700 to $2,000	$0 M to $2 M

that Replaces Case of Moving Directly to Seizure				
Admini-strative Detention that Replaces Class I Recall	0 to 184	0	$1,700 to $2,000	$0
Admini-strative Detention that Replaces Referral to States	0 to 23	0 to 2,323	$1,700 to $2,000	$0 to $2 M
Total				$0 M to $42 M

Storage

The cost of storing food in secure storage facilities depends on the following factors: 1) level of security of the

facility; 2) type of food; 3) length of time the food is stored; 4) amount of food; and 5) miscellaneous factors, such as geographic location of facility, whether the customer is a regular or repeat customer, volume discounts, etc.

We do not define the security requirements for storage facilities in this rule. Instead, we will determine the relevant level of security on a case-by-case basis. We tentatively assume that the normal or average level of security that we would require is the level associated with bonded or third party public warehouses. Using these warehouses should provide some additional security because the owner of the food relinquishes custody of the food to the warehouse. In some cases, we might require higher security, such as that associated with secure government storage facilities, for example, Customs Examination Stations. In other cases, we might require lower security, such as that associated with a firm's own warehouses. We understand from a discussion with a representative of the International Association of Refrigerated Warehouses that the cost difference between bonded and non-bonded public warehouses is probably quite small. (Ref. 2) Therefore, we use the same storage costs for both bonded and non-bonded warehouses.

Storage costs vary with the type of food being stored. However, we were unable to find data on average storage rates for

different types of food under different conditions. (Ref. 2) One cold storage facility gave us food storage rates that varied from $0.0002 to $0.0006 per pound per month for a range of food types. (Ref. 3) Rates for food that does not need to be refrigerated might be lower than the lower bound of the rates for cold storage. However, we do not have information on these rates, and we assume that these rates will fall in the same range. The same source listed handling rates per shipment of $0.01 to $0.02 per pound. We request comments on these rates. These rates imply storage costs of $0 to $600 per day per administrative detention, and handling rates of $0 to $21,000 per administrative detention.

We estimate overall storage costs based on the handling fee per pound, the storage costs per pound per day, the amount of food we might administratively detain, and the change in the maximum number of days that we might require firms to store the food. We assume that there would be no increase in storage costs if we substituted an administrative detention action for a Class I recall, because firms probably already store food as part of such a recall. There is no storage associated with taking no preliminary enforcement action prior to a seizure action or a referral of a ~~problem~~ matter to a state authority. Therefore, any storage associated with an administrative detention would be

an additional cost in comparison to moving directly to seizure or referring a ~~problem~~ matter to a state authority.

Administrative detention involves a maximum storage time of up to 30 days. The actual amount of time that firms would store detained food depends on whether and when they appeal the administrative detention order. Firms would appeal if they expected the costs of doing so would be less than the costs of storing the food until we completed our investigation, or until the detention period expired. We have insufficient information to estimate the percentage of administrative detentions that firms would appeal. Therefore, we use a maximum of 30 days additional storage time for all administrative detentions. We do not know how long firms store food that they voluntarily recall before reconditioning or destroying the food. We tentatively assume that the storage time associated with Class I recalls would be similar to the storage time associated with administrative detention.

We provide estimates of annual storage costs, rounded to the nearest million dollars, in Table ~~4~~3.

Table ~~4~~ 3 - Annual Storage					

Costs					
~~Action Replaced by Administrative Detention~~ Action	~~Number of Substitutions~~ Number of Actions	~~Change in Days Storage per Substitution~~ Change in Days Storage per Action	~~Cost per Day (based on average shipment)~~ Cost per Day (based on average ship-Ment)	~~Handling Cost per Administrative Detention~~ Handling Cost per Action	Change in Total Storage Cost (in millions)
~~No preliminary action (move directly to seizure)~~ Administrative Detention that Replaces Case of Moving Directly to	0 to 16	0 to 30	$0 to $500	$0 to $21,000	$0 ~~M~~ to $1 ~~M~~

Seizure					
~~Class I recalls~~ Administrative Detention that Replaces Class I Recall	0 to 184	0	$0 to $500	$0 to $21,000	$0 M
Administrative Detention that Replaces Referral to State	0 to 23	0 to 30	$0 to $500	$0 to $21,000	$0 to $1 M
Total					$0 M to $21 M

Loss of product value over detention period, if we later find the product is not violative.

Food may lose some or all of its value during an administrative detention because the food may deteriorate, and because firms would have less time to sell food that has a finite shelf life. Reducing the time available to sell food reduces the

value of that food because consumers only desire a given quantity of a particular food in a particular time period. In order to sell additional units of that food during that time period, retailers would need to lower the price of the food to reflect the value consumers place on the additional units. This cost is only relevant if we determine that the food does not present a threat of serious adverse health consequence or death to humans or animals and, therefore, terminate the detention and release the food back into commerce. The loss of product value would not be relevant for detained food found to be violative because such food would have lost its value due to its violative nature, rather than the administrative detention.

We have not estimated costs connected to the marking or labeling food that we administratively detain. As we discussed earlier in this preamble, if we required marking or labeling of food in conjunction with an administrative detention order, and we subsequently cancelled the administrative detention order, then we would remove, or authorize the removal of, the marks or labels. Therefore, we assume there will not be any loss of value from the marking or labeling requirements contained in this proposed rule.

Administrative detention actions might also cause food that we do not administratively detain to lose value if delivery of

that food to its final destination were delayed as a result of being packed together with food that we did detain. We have not included the potential loss of value from this source~~,~~ because, based on our experience with other enforcement actions, we expect that we will not cause significant delays in the delivery of food that is packed with food that we administratively detain.

Loss of value over the detention period depends on the following factors: 1) shelf life of the food under usual storage conditions; 2) rate of value loss over time; and 3) starting value of the food.

The loss of value depends on the shelf life of the food because the longer the shelf life, the less the food will deteriorate during a given time period, and the smaller the proportional reduction in the time remaining to sell the food. For purposes of this analysis, we have designated four shelf life categories:

- Perishable food. We define perishable food for purposes of this analysis as food having a shelf life of seven days or less. This is based on the definition of perishable food discussed earlier in this preamble (i.e. perishable food is food that is not heat-treated; not frozen; and not otherwise preserved in a manner so as to prevent the quality of the

food from being adversely affected if held longer than 7 days under normal shipping and storage conditions.) Examples of this type of food include fluid milk that has not been ultra-pasteurized; live fish, lobster, crab, other crustaceans, shellfish; and fresh fruits and vegetables. (See Ref. 5)

- Food having a shelf life of between eight and thirty days. Food with this shelf life that we regulate include some fresh and processed dairy products, including soft cheeses such as cottage cheese; some bakery items, such as bread, rolls, cakes, pies, and cookies; poultry; and some fruit and vegetable products. (Ref. 6) These examples are derived from a list of examples developed by Hurst et al., but do not include products listed as examples in our RPM definition of "perishable commodity."

- Food having a shelf life of between thirty and ninety days. These types of food include dairy products, such as butter, margarine, natural hard cheese, processed hard cheese, and ice cream; eggs; some picked food; processed salads; some fruit and vegetable products; cured meats; fatty meats such as luncheon meats, ground beef, lamb and pork; fatty fish

such as mackerel; shellfish; giblets; some frozen bakery food, such as cake batter, pie shells, fruit pies, yeast breads and rolls, frozen bread and roll dough~~)~~; fried snack food such as potato chips; frozen convenience food such as pre-cooked combination dinners and frozen french fries; dried bakery products such as cookies and crackers; beverages such as ground coffee that is not vacuum packed; canned pickled fish; powdered cream; and fats and oils such as mayonnaise, salad dressing, and vegetable shortening. (Ref. 6)

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- Food having a shelf life of over ~~ninety~~ 90 days.

The only type of enforcement action for which we have readily available data on the type of food involved is imported food that we have refused entry into the United States. Therefore, we used these data for analysis, because we expect the distribution of food by type for domestic food to be similar. The food categories in these data do not correspond precisely to the shelf life categories just discussed. If a food category covered more than one shelf life category, we assumed that an equal amount of the product in that category belonged to each relevant shelf life category. Based on these assumptions and

definitions, approximately twenty percent of the imported food that we refused entry into the United States from August 2001 through July 2002 was perishable under the definition in this proposed rule, twenty percent of the food had a shelf life of eight to 30 days, thirty percent had a shelf life of 31 to 90 days, and thirty percent had a shelf life of 91 days and over.

The rate of value loss over time varies with the type of food involved. To simplify our analysis, we assumed that all perishable food (i.e. food with a shelf life of up to seven days) would lose a fixed amount of its starting value each day, such that its value would drop to zero by the end of day seven. This corresponds to a value loss of about 14 percent of the starting value per day. The comparable rates for products with a shelf life of between eight and thirty days, and between thirty-one and ninety days, were 3 percent and 1 percent, respectively. We tentatively assume that products with a shelf life of 91 days or more will not lose value during an administrative detention.

In order to apply these rates of value loss, we need the starting value of the food that we would administratively detain. We previously assumed that we would administratively detain 0 to 1 million pounds of food per administrative detention action. The value of this quantity of food would vary considerably with the type of food involved. To estimate an average value, we used

the average value of a line of imported food because those data were readily available. After estimating the average value of a line of imported food, we then divide that value by the previously estimated average size of a line of imported food, which was 15,000 pounds, to get an average value per pound. We then multiply that value by 0 to 1 million pounds to arrive at the average value of the amount of food that we might administratively detain. According to U.S. Commerce Department data, the value of imports of food, feeds, and beverages into the United States in 2001 was approximately $47 billion. (Ref. 7) To relate the total value to the value of an average line for those types of food, we extrapolated data on the number of lines in the OASIS system for the three quarters of FY 2002 for human and animal food to estimate a total of approximately four million lines for human and animal food by the end of fiscal year 2002. This implies an average value per line of about $11,000. We did not have information on the value of other types of imported food, such as dietary supplements or live animals. Therefore, we assumed that the average value per line for all types of food is approximately $11,000. If an average line is 15,000 pounds, then this corresponds to a value per pound of $0.73. Therefore, the value of 0 to 1 million pounds would be $0 to $730,000. Based on the rates of value loss given earlier, the average loss of value

per administrative detention action per day would be $0 to $102,000 for perishable food, and $0 to $10,000 per day for non-perishable food.

We have set the maximum time frame for all administratively detained food, including perishable food, at 30 days. Therefore, we calculated the loss of value for all food based on 0 to 30 days of additional storage. As we discussed earlier in the preamble, we intend in the case of perishable food to send a seizure recommendation to the Department of Justice within four calendar days after we issue an administrative detention order, unless extenuating circumstances exist. However, we do not know how often extenuating circumstances will exist, or how much time will elapse between our recommendation and the subsequent seizure.

We do not estimate any change in the loss of value if we substitute an administrative detention action for a Class I recall request, because we previously assumed that substituting an administrative detention action for a Class I recall would not change the amount of time a firm would store the food in question. Therefore, any loss of value resulting from taking action against food that was actually not violative would be the same under either type of action. In contrast, there is no storage associated with moving directly to a seizure action or

referring a ~~problem~~ matter to state authorities. Therefore, any loss of value from storage associated with an administrative detention action would be an additional cost in those~~that~~ cases.

We provide estimates of the value loss for food in Table ~~5~~4.

Table ~~5~~ 4 - Annual Loss of Value			
Action ~~Replaced by Administrative Detention~~	**Number of ~~Substitutions~~ Actions in which Product Not Violative**	**Change in Days Storage per Action ~~Substitution~~**	**Change in Total Loss of Value (in millions)**
~~No preliminary action (move directly to seizure)~~ Administrative Detention that Replaces Case of Moving Directly to Seizure	0 to 8	0 to 30	$0 to $6 M
~~Class I recall~~ Administrative Detention that Replaces Class I Recall	0 to 88	0	$0 M